

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	1.3 g in 100 mL		
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	17.4 g in 100 mL		
Inactive Ingredients				
Ingredient Name	Strength			
GLYCERIN (UNII: PDC6A3C00X)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
METHYL DIHYDROABIETATE (UNII: 7666FJ0J9F)				
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)				
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)				
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
FERRIC OXIDE RED (UNII: 1K09F3G675)				
FERROSOFERRIC OXIDE (UNII: XM0M87F357)				
HEDYCHIUM CORONARIUM ROOT (UNII: 92A6N0IQN9)				
LEUCONOSTOC/RADISH ROOT FERMENT FILTRATE (UNII: D2QHA03458)				
DIMETHICONE (UNII: 92RU3N3Y1O)				
DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)				
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)				
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)				
WATER (UNII: 059QF0K00R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75936-281-01	5 mL in 1 TUBE; Type 0: Not a Combination Product	05/18/2021	
2	NDC:75936-281-02	10 mL in 1 TUBE; Type 0: Not a Combination Product	05/18/2021	
3	NDC:75936-281-03	45 mL in 1 CARTON; Type 0: Not a Combination Product	05/18/2021	
4	NDC:75936-281-04	20 mL in 1 TUBE; Type 0: Not a Combination Product	09/02/2021	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final		part352	05/18/2021	

Labeler - Taylor James Ltd. (033381850)

Registrant - Englewood Lab, Inc. (080987545)

Establishment

Name	Address	ID/FEI	Business Operations
Englewood Lab, Inc.		080987545	manufacture(75936-281)

Revised: 8/2021

Taylor James Ltd.